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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/529,128

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GRAHAM FRANCOIS DUIRS

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

07/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/529,128	Applicant(s) DUIRS, GRAHAM FRANCOIS	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,9,11-14 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8,9,11-14 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 4/28/2008.
2. In the reply, the applicant amended claims 1, 3 and added new claim 21.
3. Thus, claims 1, 3-5, 8-9, 11-14, 17-21 are pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4-5, 8, 12-13, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiller et al (4369783). Hiller et al discloses an internal substance delivery device for insertion into a body cavity (Summary), the device includes a support frame (1) having at least two resilient arms (two biased angled arms of 1 that connect to 4a and 4a) which retain the internal substance delivery device against a mucosal membrane of the body cavity (col 1, lns 12-45; col 2, lns 66-col 3, lns 7), wherein each resilient arm is capable of receiving and releasing a separate pod (4a, 4a; Fig 1-17) capable of releasing a drug contained within a matrix of the pod into the body cavity (Figs 1-17; 4a, col 4, lns 37-col 5, lns 51), and wherein the at least two resilient arms are biased outward from a central section (Figs 1-17; central section of 1 before angled curve (see Fig 1)) of the support frame; wherein at least one of the pods is flexibly attached to a corresponding arm by a ball and socket mechanism (Fig 1-17; 4a, 3; col 3,

Ins 8-11) allowing full movement or 3-dimensional movement of the pod with respect to the support frame and enabling the internal substance delivery device to contact the mucosal membrane of the body cavity (col 1, Ins 12-45; col 2, Ins 66-col 3, Ins 20); wherein the substance is released from the pod through osmosis (col 5, Ins 30-42); wherein the pod is rounded (col 4, Ins 22-25); wherein at least one of the pods is flexibly attached to a corresponding arm (Fig 1-17; col 3, Ins 8-11); wherein the at least two resilient arms are sufficiently pliable to be moved together to allow the substance delivery device to be effectively compressed (Figs 1-17; Summary); wherein the at least two resilient arms are capable of interlocking for removal or insertion (Figs 1-17; Summary). Additionally, see Response to Arguments below.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al. Hiller et al discloses the invention substantially as claimed except for expressly disclose the support frame being made out of nylon. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the support frame out of nylon because the Applicant has not disclosed that making the support frame out of nylon provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in

the art would have expected the Applicants invention to perform equally well with the support frame material of Anderson et al because the material performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Hiller et al to obtain the invention as specified in claim 11.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al. Hiller et al discloses the invention substantially as claimed except for expressly disclosing that the matrix is a cellulose matrix. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the matrix be of cellulose because the Applicant has not disclosed that having the matrix be specifically made of cellulose provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the matrix (col 5, lns 34-37; col 10, lns 38-44) of Anderson et al because the matrix performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Hiller et al to obtain the invention as specified in claim 20.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al in view of Anderson et al (5816248). Hiller et al discloses the invention substantially as claimed except for expressly disclosing wherein the device is an intra-vaginal release device. However, the device of Hiller et al is a prophylactic device structurally shaped and capable of vaginal placement. Anderson et al teaches that it is known to have a

intra-vaginal release device (Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37) for the purpose of delivering an agent to the urogenital tract. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Hiller et al with the intra-vaginal device as taught by Anderson et al for the purpose of delivering an agent to the urogenital tract.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al in view of Anderson et al (5816248). Hiller et al discloses the invention substantially as claimed except for expressly disclosing wherein the support frame is in the form of a wish bone. Anderson et al teaches that it is known to have wherein the support frame is in the form of a wish bone (Fig 3) for the purpose of implantable placement in the urogenital tract. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the support frame as taught by Hiller et al with the wish bone shaped support frame as taught by Anderson et al for the purpose of implantable placement in the urogenital tract.

11. Claims 14, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al in view of Anderson et al (5816248). Hiller et al discloses the invention substantially as claimed except for expressly disclosing wherein the support frame includes a locator. Anderson et al teaches that it is known to have wherein the support frame includes a locator (68, Abstract, col 3, lns 52-57; col 4, lns 18-col 5, lns 37) for the purpose of correct positioning of the device inside the vaginal region. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the support frame as taught by Hiller et al with the locator as taught by

Anderson et al for the purpose of correct positioning of the device inside the vaginal region.

Response to Arguments

12. Applicant's arguments filed 4/28/2008 have been fully considered but they are not persuasive.

13. The applicant argues that:

i. Hiller et al does not disclose two resilient arms that are biased outward from the support frame and wherein at least one pod is allowed full movement with respect to the support frame (Remarks, pg 7, paragraph 1-2).

ii. Anderson fails to teach or suggest wherein at least one pod is flexibly attached to the corresponding arm by a ball and socket mechanism allowing full movement of the pod with respect to the support frame (Remarks, pg 9, paragraph 3).

14. In response to the applicant's argument (i), the Examiner notes that because the arms of the support frame (1) of Hiller et al are resilient (col 2, lns 8-12), the arms are fully capable of being biased outward from a central section of the support frame. In one sense, the ends of the arms (2; Fig 1) are biased outward from the central section of the support frame (1) as shown in Figure 1 because the arms are not touching and if one tried to get the ends of the arms to touch, the resilience present in the arms would resist the inward force and attempt to bias the arms outward to their resting position shown in Fig 1. A recitation of the intended use of the claimed invention must result in a

structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Hiller et al further discloses that's the size and angle of the support frame and arms can change to accommodate different sizes of subjects (ie calf vs adult cattle). The device of Hiller et al is fully capable of being placed into a body cavity having a mucosal membrane and the body cavity is sized such that the arms of the support frame must be compressed from a resting state to effectively place the device inside the body cavity and upon release the arms will bias outward – attempting to return to the resting position, such as the position shown in Fig 1, and the arms will provide outward bias against the mucosal membrane wall of of the body cavity.

15. In response to the applicant's argument (ii), the Examiner notes that the statements regarding Anderson are moot because Hiller et al substantially discloses those claimed features. The device of Anderson is merely being used as a secondary reference teaching that it is well known in the art to have an intra-vaginal substance delivery whose support frame is in the form of a wish bone and includes a locator as discussed above in the rejections. The Examiner further notes that Hiller et al discloses a pod that is flexibly attached to a corresponding arm by a ball and socket mechanism allowing full movement or 3-D movement of the pod with respect to the support frame (col 3, Ins 8-21; specifically detailing that the connection may be a ball and socket mechanism with a freely moveable connection manner for the proper angle being formed automatically).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767